



Medical Products and Services

K964777
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510(K) SUMMARY

OWNER: Gallini s.r.l.
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U.S. Representative

SUBMISSION DATE: November 22, 1996

DEVICE NAME: "TZ®" Biopsy Needle

PREDICATE DEVICE: ProMedical Ltd. - PRO-B Biopsy Needle
510(K)# - K951598

**DESCRIPTION OF
DEVICE FUNCTION:** The device is a spring loaded, disposable biopsy
needle.

INTENDED USE: This device is intended to be used to take high
quality histological core samples from soft tissue,
including (but not limited to) liver, kidney, prostate.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The "TZ®" Biopsy needle is identical to the predicate devices in terms of technological characteristics.

The following tests were performed to demonstrate the safety and efficacy of the device.

TEST	RESULT
Firing Test	Passed
Pyrogen Test (LAL)	Passed
Biocompatibility	All tests are performed by the raw material suppliers.